



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 19 1999

5310 '99 FEB 23 P1:49

Ms. Gloria S. Donovan
Legal Assistant
Metagenics, Inc.
971 Calle Negocio
San Clemente, California 92673

Dear Ms. Donovan:

This is in response to your letter of February 8, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Metagenics, Inc. is marketing the dietary supplements Metagenics Brand Fem Osteo™ and Metapharma Brand Osteo Essentials™, Osteo Essentials-MG™, and Osteo Firm Plus™ bearing the claim, among others, that they "can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength."

This statement does not appear to be a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to section 21 U.S.C. 343(r)(1)(B) for which FDA has authorized a health claim under 21 U.S.C. 343(r)(5)(D) (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 25

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#63753)

HFD-310 (BWilliams)

HFD-314 (Aronson)

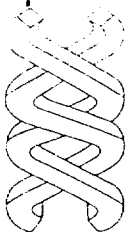
HFS-605 (Bowers)

HFV-228 (Benz)

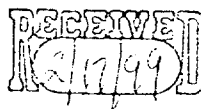
HFV-232 (Brown)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:2/18/99:docname:63753.adv:disc35



Metagenics
Genetic Potential Through Nutrition



63753

February 8, 1999

Office of Special Nutritionals
Center for Food Safety And Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Certified Mail
Return Receipt
P 268 918 957

Re: Structure Function Claims/FDA Notification

Dear Sir or Madam:

Enclosed please find the above document prepared in accordance with the proposed regulation 21 C.F.R. Section 101.93.

Should you have any questions or comments, please do not hesitate to contact Beverly Chin or me at the above number.

Sincerely,

Gloria S. Donovan
Legal Assistant

Enclosure

cc: Beverly Chin, Esq.

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S. C 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Metagenics, Inc. with its principal place of business at 971 Calle Negocio, San Clemente, California 92673, (714) 366-0818, has commenced marketing the following dietary supplements bearing the following statement(s) on the label and/or in the labeling:

METAGENICS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
BIO – SCORB™	Vitamin C; Bioflavonoids	In addition to its well-known function as an antioxidant, Vitamin C is essential for collagen production and plays an important role in immune function. Bioflavonoids function as an antioxidant and may help support healthy capillary permeability.
CAL APATITE® with Magnesium	Magnesium	Magnesium plays important roles in bone metabolism, with over one-half of the total body stores of magnesium found in bone tissue.
CAL-APATITE® with Boron	Boron	Boron may play a role in maintaining healthy calcium balance possibly through involvement in estrogen and vitamin D metabolism.
CAL MATRIX™	Calcium; Microcrystalline Hydroxyapatite Concentrate; Vitamin D; Glucosamine Sulfate; Vitamin C; Phosphorus; Manganese; Magnesium; zinc; copper; boron; chromium	Provides nutritional support for healthy bones and joint tissue. Offers comprehensive bone nourishment with vitamin D and calcium-rich microcrystalline hydroxyapatite concentrate.

COLLAGENICS® INTENSIVE CARE FORMULA	D-Glucosamine Sulfate; Proanthocyanidin; Vitamin E; Vitamin C; Zinc Glycinate; Copper Glycinate; Manganese Glycinate	Nutritional support for soft and connective tissue. The formula also supplies patented mineral amino acid chelates that provide precursors for the production of intracellular superoxide dismutase (SOD).
CoQ-10 ST	Coenzyme Q10	Coenzyme Q10 plays an important role in the body's production of energy and also has antioxidant properties.
CORDEPHRINE PRO™	Cordyceps Mycelia	Cordyceps also contains chemical components such as Adenosine. Adenosine is the Nucleoside backbone for ATP - the energy molecule for human life.
FEM OSTEO™	Calcium	Calcium, along with exercise and a healthy diet, can play a significant role in reducing the rate of bone loss or bone thinning and protecting bone strength. Magnesium plays important roles in bone metabolism and muscle relaxation, helping transport calcium into bone and soft tissues.
FEM PROTECT™	Vitamin A; Vitamin E; Folic acid; Salvia root; Ginger rhizome; White Peony root; Licorice root; Calcium d- glucarate; Tumeric rhizome	Designed to provide antioxidant protection for women. Features a unique blend of essential nutrients such as vitamins A, C, and E for antioxidant and immune system support, folic acid and vitamin E to support cardiovascular health, and select Asian herbal extracts traditionally used to support healthy blood circulation. These are combined with the novel components, calcium d- glucarate to support breast tissue health and curcumin C3 complex, which provides the

		cardiovascular system and the immune system.
MALIC SYNERGY™	Vitamin B1; Vitamin B6; Magnesium; Manganese; Malic Acid.	<p>Nutritional support for neuromuscular function.</p> <p>A highly specialized formula that provides nutritional support for energy metabolism and neuromuscular functions. with chelated magnesium, malic acid, and B vitamins.</p>
MENTAHERB COMPLEX™	Bacopa Whole Plant; Gotu Kola Leaf; Trailing Eclipta Leaf; Indian Gall Fruit; Ashwagandha Root; Amla Fruit; Beleric Myrobalan Fruit; Heart-leaved Moonseed Leaf and Stem; Convolvulus Whole Plant; Indian Valerian Leaf; Nutmeg Fruit; Asparagus Root; Cardamom Seed; Ginger Root; Indian Spikenard Root-stem; Giant Potato Root	<p>Combines herbs traditionally used within the ancient system of Ayurveda to nourish the brain and to help support mental function, alertness, and memory.</p> <p>This unique formula also contains herbs traditionally used to maintain a positive mood and promote a sense of calm.</p>
MINERAL SELECT™	Calcium; Magnesium	Provides the extra calcium you may need while significantly boosting your magnesium intake. minerals that are both essential for good bone health and muscle function.
MYO NUTRIENTS™	Magnesium; Calcium	A specialized formula that supplies bioavailable forms of calcium and magnesium. which play a role in muscle contraction and relaxation.
MYO NUTRIENTS-PM™	Magnesium; Calcium; Passion Flower; Valerian Root; Hop Flower; Kava Kava Root	<p>A specialized formula that supplies bioavailable forms of calcium and magnesium. which play a role in muscle contraction and relaxation</p> <p>These minerals are blended with valerian, hops, and kava kava, herbs traditionally used to relax the mind and body.</p> <p>Kava Kava and hops are traditionally used to support relaxation.</p>
OSTEO ESSENTIALS™	Microcrystalline hydroxyapatite concentrate; Calcium	<p>Bone support formula.</p> <p>Calcium, along with regular exercise and a healthy diet, can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength.</p>

		Designed to help and maintain strong healthy bones.
OSTEO ESSENTIALS-MG™	Microcrystalline Hydroxyapatite Concentrate; Calcium; Magnesium	<p>Designed to help women build and maintain strong, healthy bones and support muscles.</p> <p>Calcium, along with exercise and a healthy diet, can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength.</p> <p>Magnesium plays important roles in bone metabolism and muscle relaxation, helping to transport calcium into bone and soft tissue.</p>
OSTEO FIRM™	Calcium; Phosphorus; Glucosamine Sulfate; Vitamin C; Manganese; Vitamin D; Magnesium; Zinc; Copper; Boron; Chromium	<p>Nutritional bone support.</p> <p>Provides nutritional support for healthy bones and joint tissue.</p> <p>Features glucosamine sulfate, targeted minerals, and vitamin C for collagen, bone matrix, and joint support.</p>
OSTEO FIRM PLUS™	Calcium; Phosphorus; Vitamin A; Vitamin E; Vitamin D; Vitamin C; Magnesium; Niacinamide; Pantothenic Acid; Vitamin B6; Riboflavin; Vitamin B1; Zinc; Copper; Manganese; Folic Acid; Quercetin; Alpha-Carotene; Cryptoxanthin; Zeaxanthin; Lutein	<p>Special nutritional support for women over 50.</p> <p>An excellent formulation providing calcium, vitamins, and minerals specially designed to provide nutritional support for menopausal and post-menopausal women.</p> <p>Provides comprehensive nutritional bone support featuring calcium-rich microcrystalline hydroxyapatite concentrate, trace minerals, and vitamin D.</p> <p>Calcium, along with exercise and a healthy diet can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength.</p>
PREMENSTRUAL HERBS™	Bupleurum Root; Peony Root; Dong Quai Root; Atractylodes Rhizome; Poria Fungus; Ginger Rhizome; Licorice Root; Peppermint Herb	<p>Herbal premenstrual support.</p> <p>An ancient chinese botanical formula traditionally used to nourish the liver and promote the flow of liver ch'i (vital force).</p>
PREMENSTRUAL NUTRIENTS™	Taurine; Vitamin C; Choline; Magnesium; Pantothenic Acid; Vitamin B6; Chasteberry Fruit;	<p>Premenstrual support formula.</p> <p>Designed to provide support to</p>